



November 22, 2021

EKOS Corporation
Jocelyn Kersten
Vice President
11911 N Creek Parkway South
Bothell, Washington 98011

Re: K081467

Trade/Device Name: EkoSonic Endovascular System With Rapid Pulse Modulation
Regulation Number: 21 CFR 870.5150
Regulation Name: Embolectomy catheter
Regulatory Class: Class II
Product Code: QEY, KRA

Dear Jocelyn Kersten:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 26, 2008. Specifically, FDA is updating this SE Letter as an administrative correction because FDA has created a new product code to better categorize your device technology.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Gregory O'Connell, OHT2: Office of Cardiovascular Devices, (301) 796-6075, Gregory.Oconnell@FDA.HHS.gov.

Sincerely,

Gregory W.
O'Connell -S

Digitally signed by
Gregory W.
O'Connell -S
Date: 2021.11.22
13:37:13 -05'00'

Gregory O'Connell
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2008

EKOS Corporation
c/o Ms. Jocelyn Kersten
Vice President, Quality Assurance, Regulatory and Clinical Affairs
11911 N Creek Pkwy S
Bothell, WA 98011

Re: K081467

Trade/Device Name: EkoSonic™ Endovascular System with Rapid Pulse Modulation
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter, Continuous Flush
Regulatory Class: Class II (two)
Product Code: KRA
Dated: May 22, 2008
Received: May 27, 2008

Dear Ms. Kersten:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

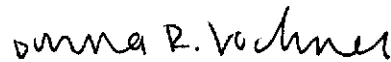
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.


Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

Bram D. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SPECIAL 510(k) Notification
EkoSonic™ Endovascular System

EKOS Corporation
11911 North Creek Parkway South
Bothell, WA 98011

Indications for Use Statement

510(k) Number (if known): K081467

Device Name: EkoSonic™ Endovascular System with Rapid Pulse Modulation

Indications for Use:

The EkoSonic™ Endovascular System with Rapid Pulse Modulation is intended for the infusion of solutions into the pulmonary arteries.

The safety and effectiveness of the EKOS EkoSonic™ Endovascular System with Rapid Pulse Modulation for thrombolytic therapy administration in pulmonary embolus have not been established. In particular, the ultrasound energy delivered by the EndoWave system is not intended to be therapeutic, nor has it been cleared with an indication for thrombolysis in pulmonary emboli.

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

JUN 26 2008

Section 4. 510(k) Summary**General Provisions**

Submitter's Name and Address: EKOS Corporation
11911 North Creek Parkway South
Bothell, WA 98011

Contact Person: Jocelyn Kersten
425-415-3132
425-415-3102 (fax)
jkersten@EKOSCORP.com

Classification Name: Catheter, Continuous Flush (KRA)

Regulation Number: 21 CFR §870.1210

Common or Usual Name: Continuous Flush Catheter

Proprietary Name: EkoSonic™ Endovascular System with Rapid Pulse Modulation

Name of Predicate Device: EndoWave Infusion System

510(k) Reference No.: K080392, K073166

Device Description

The system consists of a disposable infusion catheter with removable ultrasound core and an instrument that generates and controls the delivery of energy to the catheter. The infusion catheter contains multiple side holes distributed over the length of the treatment zone. The ultrasound core contains up to 30 ultrasound elements, evenly spaced over the treatment zone. Thermal sensors in the treatment zone monitor catheter temperature.

Intended Use

The EkoSonic System is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature.

SPECIAL 510(k) Notification
EkoSonic™ Endovascular System

The EkoSonic™ Endovascular System with Rapid Pulse Modulation is intended for the infusion of solutions into the pulmonary arteries.

The safety and effectiveness of the EKOS EkoSonic™ Endovascular System with Rapid Pulse Modulation for thrombolytic therapy administration in pulmonary embolus have not been established. In particular, the ultrasound energy delivered by the EndoWave system is not intended to be therapeutic, nor has it been cleared with an indication for thrombolysis in pulmonary emboli.

Summary of Technological Characteristics

The device modification described in this notification does not affect the technological characteristics for the EkoSonic System.

Test Summary

Electrical safety testing, electrical circuit qualification testing, software validation testing and system integration testing confirmed the modified EkoSonic System is substantially equivalent to the predicate EndoWave System.